In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 7, 2025

KELSEY DOBBS, on behalf of S.S., a minor child,	*	PUBLISHED
Petitioner,	*	No. 21-2073V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Fact Finding; Site of Vaccination.
Respondent.	*	

Diana Lynn Stadelnikas, Mctlaw, Sarasota, FL, for Petitioner.
Felicia Langel, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING[1]

On October 26, 2021, Kelsey Dobbs ("Petitioner"), on behalf of S.S., a minor child, filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).[2] Petitioner alleges that S.S. suffered lipodystrophy as the result of, or significantly aggravated by, Pentacel (diphtheria-tetanus-acellular pertussis ("DTaP")-*Haemophilus influenzae* B ("Hib")-inactivated poliovirus

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

("IPV")), pneumococcal conjugate ("PCV"), and/or hepatitis B ("Hep B") vaccinations administered on November 25, 2019. Petition at 1, 4 (ECF No. 1). On December 7, 2022, Respondent filed his Rule 4(c) report, arguing Petitioner failed to provide preponderant evidence in support of her petition. Respondent's Report ("Resp. Rept.") at 2, 10-13 (ECF No. 29).

The parties have been unable to resolve the issue of site of vaccination and requested that the Court make a fact finding. Since then, the parties' briefs have been filed and this matter is ripe for adjudication on the present issue.

Upon consideration of the record as a whole, the undersigned finds S.S.'s November 25, 2019 vaccination(s) were administered in her left thigh.

I. PROCEDURAL HISTORY

Petitioner filed her petition on October 26, 2021, following by medical records and an affidavit in November 2021 and May 2022.[3] Petition; Petitioner's Exhibits ("Pet. Exs.") 1-13. This case was assigned to the undersigned in December 2021. Notice of Reassignment dated Dec. 15, 2021 (ECF No. 9).

On December 7, 2022, Respondent filed his Rule 4(c) report, noting several issues in Petitioner's case and arguing Petitioner failed to provide preponderant evidence in support of the petition. Resp. Rept. at 2, 10-13. Thereafter, from December 2022 to April 2023, Petitioner filed additional medical records, photographs, and evidence in support of her claim. Pet. Exs. 14-29.

In May 2023, the parties requested to file expert reports as Respondent wished to continue to defend the matter. Order dated May 19, 2023 (ECF No. 56). On September 20, 2023, Petitioner filed an expert report from Dr. Kyle Amber. Pet. Ex. 31. On February 2, 2024, Respondent filed an expert report from Dr. Ginette A. Okoye. Resp. Ex. A. Petitioner filed a supplemental report from Dr. Amber on June 5, 2024. Pet. Ex. 57.

Thereafter, pursuant to the parties' request, a Rule 5 conference was held on June 25, 2024. Rule 5 Order dated June 26, 2024 (ECF No. 75). The undersigned preliminarily found that the location of the vaccines at issue were given in S.S.'s left thigh. Id. at 1. This finding was based on the family's reports to healthcare providers in the weeks after vaccination, which were consistent and documented by at least three different providers. Id. The undersigned also noted the experts agreed that injection site lipodystrophy is the correct diagnosis. Id.

Following the Rule 5 conference, Respondent requested that the Court issue a fact ruling on the site of administration of the vaccines at issue in this case. Joint Status Rept., filed July 24, 2024 (ECF No. 76). The parties each filed briefs on September 25, 2024. Resp. Brief Regarding Site of Vaccination ("Resp. Br."), filed Sept. 25, 2024 (ECF No. 82); Pet. Motion for Findings of Fact Regarding Vaccination Site of Administration ("Pet. Br."), filed Sept. 25, 2024 (ECF No. 83).

[3] Medical records were filed throughout litigation.

This matter is now ripe for adjudication.

II. RELEVANT MEDICAL RECORD HISTORY[4]

S.S. was born on May 24, 2019 at 37 weeks and four days gestation via Cesarean section. Pet. Ex. 11 at 196-201. S.S. received her first Hep B vaccination that same day. Pet. Ex. 8 at 1. Of note, the official immunization record from the Oklahoma State Department of Health ("OSDH") does not indicate the route or site of administration for this vaccination or any vaccine administered to S.S. See id. at 1-2.

S.S., at two months old, received her first DTaP, Hib, IPV, PCV, and rotavirus vaccines and her second Hep B vaccine at OSDH on July 24, 2019. Pet. Ex. 8 at 1. On September 24, 2019, at four months old, S.S. received her second DTaP, Hib, IPV, PCV, and rotavirus vaccines at OSDH. Id. The route and site of administration for these vaccines were not indicated. See id.

On October 30, 2019, S.S. saw her pediatric primary care provider ("PCP") Terry Draper, FNP, for runny nose, congestion, shortness of breath, ear pain, and a cough. Pet. Ex. 6 at 74. S.S. was diagnosed with sinusitis and was administered Kenalog intramuscularly into her right hip and clindamycin intramuscularly into her left hip. Id. at 78. No other injections were administered.

On November 25, 2019, at six months old, S.S. received her third DTaP, Hib, IPV, PCV, and Hep B vaccines at OSDH. Pet. Ex. 8 at 1. Again, the route and site of administration was not indicated. See id.

S.S. returned to her PCP on December 2, 2019, with complaints of vomiting, diarrhea, and inappetence. Pet. Ex. 6 at 80. On examination, FNP Draper noted that S.S. had lost weight and appeared colic-like. Id. at 82-83. FNP Draper diagnosed S.S. with failure to thrive and possible pyloric stenosis, and she referred S.S. to a gastroenterologist. Id. at 84. No abnormalities of S.S.'s left thigh were noted. See id. at 80-85.

On December 26, 2019, S.S. saw her PCP for a "large, bruised area on her right[5] thigh where she received her [six] month old immunizations [from] [OSDH]." Pet. Ex. 6 at 86. When S.S. was in a standing position, "the discolored area becomes an indentation in her left thigh" and "[h]er left foot rolls inward" when standing with assistance. Id. On physical examination, range of motion testing revealed restriction and instability of the left quadricep. Id. at 88. The muscle was noted to retract inward toward the leg when S.S. stood. Id. Diagnoses included unspecified superficial injury of left thigh and muscle wasting and atrophy of left thigh. Id. at

[4] The undersigned has reviewed all of medical records, but summarizes only those pertinent to the factual issue here.

[5] The experts and the undersigned agree this appears to be an error as all other records discuss and document the indentation to be on the left thigh. See Pet. Ex. 31 at 2; Resp. Ex. A at 2.

89. X-ray and ultrasound of the left thigh were ordered and S.S. was referred to an orthopedist. Id. at 90.

On February 3, 2020, S.S. had an evaluation with orthopedic specialist, Joseph Davy, M.D. Pet. Ex. 1 at 46. At this visit, Petitioner filled out a patient form for S.S. noting the problem as "[i]ndentation on left leg from [six] month shots," with an onset of one week post-vaccination. Id. at 49. Dr. Davy's history of present illness documented that "at the time of her [six] month shots, which was a [DTaP] and [IPV], [S.S.] developed a dent in the anterior thigh." Id. at 46. Petitioner also reported that S.S. was reluctant to use her left leg when crawling, but that it was not painful. Id. Physical examination showed "soft tissue defect in the anterior thigh about at the mid portion" that appeared to be at the subcutaneous tissue level and non-tender. Id. Dr. Davy was able to feel her quadriceps, noting "it was functional." Id. Dr. Davy's assessment was "[s]oft tissue defect after prior immunization." Id. He opined, "I think that the immunization got into the body and was absorbed and was able to be effective for her. It is possible that [the vaccines] ended up being in the subcutaneous tissue more than the muscle and has resulted in some fatty necrosis." Id. Dr. Davey determined that the left thigh lesion was "primarily a cosmetic problem," and he recommended that S.S. see a plastic surgeon if the lesion persisted after "a couple of years." Id.

On April 29, 2020, Petitioner sought a second opinion for S.S.'s "indentation to soft tissue on left upper leg after immunization" on November 25, 2019. Pet. Ex. 24 at 15. Stormi McKnight NP conducted a physical examination and documented "atrophy to left upper thigh following immunizations." Id. at 16.

S.S. returned to her PCP on May 6, 2020 "for a referral for a plastic surgeon due to left leg muscle [] separating due to Nov[ember] 25th [] [DTaP] [IPV] injections which caused tissue damage" that "ha[d] extended into a larger area as she has grown." Pet. Ex. 6 at 120. S.S. pulled on her left leg when walking and standing due to pain and discomfort. Id. Examination noted a "deformi[t]y in her left thigh due to tissue deterioration from injections in her thigh that caused muscle and tissue damage," "signs of muscle atrophy in the left quadriceps," tenderness on palpation, and no restriction on range of motion but "possible instability of the left leg." Id. at 123. Her PCP wrote, "This patient has trauma on her left thigh due to Nov[ember] 25th inj[ections] of [DTaP] and [IPV]." Id. (emphasis omitted). S.S. was referred to plastic surgery. Id. at 124.

On May 28, 2020, S.S. saw Christian El Amm, M.D., for a plastic surgery consultation. Pet. Ex. 1 at 35. S.S. had a "[l]arge left anterior thigh granuloma with cicatricial depression and fat atrophy extending into left inguinal post immunization." Id. at 36. The "[l]eft anterior thigh area of depression with superficial cutaneous scar measur[ed] [3 cm x 4 cm]." Id. at 38. Diagnosis was "[p]ost injection granulomatous reaction with significant cicatricial changes and fat atrophy." Id.

S.S. saw plastic surgeon Scott A Newborough, M.D., on June 16, 2020 for "[s]car of the left thigh status post vaccination." Pet. Ex. 2 at 4. Dr. Newborough wrote, "[Petitioner] state[d] that [S.S.] underwent her [six] month vaccinations including DTaP, [Hep] B[,] and [IPV] in her left medial upper leg . . . on November 25. By December 3[,] [S.S.] demonstrated what

[Petitioner] describe[d] as a bruised area on the leg." Id. He noted that "[o]ver the course of the next several months[,] the area began to become more concave and extended medially and superiorly towards the groin." Id. Photographs shown during the visit showed "a patchy erythematous region," according to Dr. Newborough. Id. Dr. Newborough's physical examination documented "[t]he left upper medial thigh demonstrate[d] an area of both skin and subcutaneous tissue atrophy with extension towards the groin where there is noted to be less subcutaneous tissue atrophy and no significant skin atrophy." Id. at 5. His assessment noted S.S. "had some type of reaction which has resulted in atrophy of the subcutaneous tissue and skin at the site of her previous vaccination." Id.

On December 9, 2020, S.S. saw her PCP for fever, diarrhea, and sinusitis. Pet. Ex. 6 at 228-32. FNP Draper administered Kenalog intramuscularly into S.S.'s left buttock and clindamycin intramuscularly into her right buttock. Id. at 232.

On January 19, 2021, S.S. returned to see her PCP. Pet. Ex. 6 at 253. Petitioner reported "discolored indentations on buttock from shots given" December 9, 2020. Id. On examination, FNP Draper noted an "indentation on [the] buttocks from [the] antibiotic injection from December 9[, 2020]," and she also noted S.S.'s left leg lesion. Id. at 255-56. S.S. was noted to have "chronic indentions due to vaccinations and antibiotic injection." Id. at 257.

No additional relevant medical records have been filed.

III. EXPERT REPORTS[6]

A. Petitioner's Expert, Dr. Kyle Amber

Dr. Amber is a board-certified dermatologist "specializ[ing] in complex medical dermatology, oncodermatology, and general dermatology." Pet. Ex. 31 at 1. He treats lipoatrophy on a regular basis, estimating more than 30 patients over the last five years. Id.

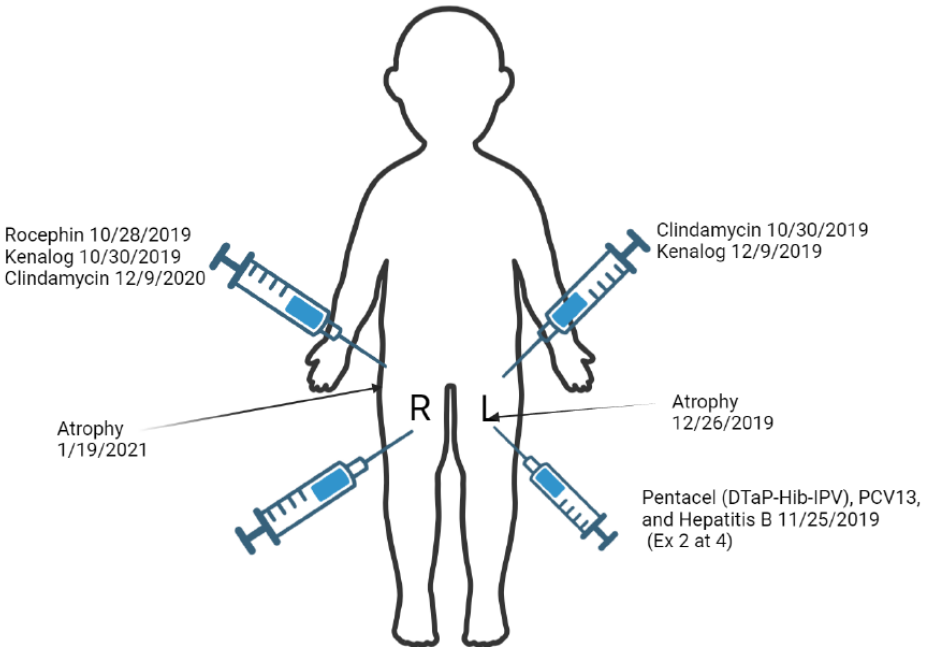
Dr. Amber opined S.S. "developed cutaneous lipoatrophy at the left thigh as a direct result of the DTaP-Hib-IPV." Pet. Ex. 31 at 4. In his supplemental report, Dr. Amber opined the left thigh lipoatrophy was "more likely than not" due to "Pentacel (DTaP-Hib-IPV), PCV[], or Hep[] B, which was given in the exact anatomical location as development of lipoatrophy." Pet. Ex. 58 at 2. He also opined "the lipoatrophy would not have occurred in the absence of an injection." Pet. Ex. 31 at 4. "[T]he development of lipoatrophy at the location of injection is consistent with this being a direct result of the injection." Id. at 6.

Dr. Amber summarized S.S.'s medical records. Pet. Ex. 31 at 2-4. Prior to the vaccinations at issue, S.S. received intramuscular Rocephin in the right thigh on October 28, 2019, intramuscular Kenalog in the right hip on October 30, 2019, and intramuscular clindamycin in the left hip on October 30, 2019. Id. at 2. On November 25, 2019, at six months of age, S.S. received the Pentacel (DTaP-Hib-IPV), PCV, and Hep B vaccinations. Id. One

[6] Only those statements and opinions that are relevant to this fact finding are included herein.

month later, on December 26, 2019, S.S. was seen for a "large bruised area" on her left thigh[7] where she received her six-month immunizations. Id. (quoting Pet. Ex. 3 at 86). Dr. Amber cited to records from various specialists that assessed Petitioner's condition as being due to her vaccinations administered on November 25, 2019. Id. at 2-3 (citing Pet. Ex. 1 at 46; Pet. Ex. 2 at 4; Pet. Ex. 6 at 199-21; Pet. Ex. 12 at 26).

Dr. Amber disagreed with Dr. Okoye's opinion that the lipoatrophy at the left thigh was due to the intramuscular injection of clindamycin in the left hip. Resp. Ex. 57 at 2. For support, Dr. Amber provided a graphic depicting all injections administered at or around the time of injury:



Id. at 1. He explained "[t]he anatomical site of left hip for intramuscular injection and the left thigh where [S.S.] has noticeable injury are clearly different anatomic sites." Id. He opined it is "highly unlikely for the drug to migrate distally to the exact location where vaccinations would be given, sparing the injection site." Id. at 3.

B. Respondent's Expert, Dr. Ginette A. Okoye

Dr. Okoye is a board-certified dermatologist. Resp. Ex. A at 1. She is "an active clinician who evaluates and treats adults and children with complex dermatologic disorders in both the inpatient and outpatient settings." Id.

Dr. Okoye opined "S.S. developed localized lipoatrophy on the left anterior thigh, and that this was triggered by intramuscular injections of clindamycin." Resp. Ex. A at 1.

[7] Dr. Amber noted this record originally documented the location as right thigh before the record was corrected. Pet. Ex. 31 at 2.

She noted S.S. received an intramuscular injection of clindamycin in the left hip on October 28, 2019. Resp. Ex. A at 2. One month later, on November 25, 2019, S.S. received the vaccinations at issue; however, the location of administration was not recorded. Id. (citing Pet. Ex. 8 at 1). On December 26, 2019, four weeks after her immunizations and approximately eight weeks after the intramuscular clindamycin injection, S.S. was seen for a "bruised area" on her left[8] thigh. Id. S.S. saw various specialists thereafter. Id. at 2-3.

Based on the medical records, clinical history, and photographs of S.S., Dr. Okoye opined "the mostly likely diagnosis is localized lipoatrophy," with "injections [as] the inciting factor." Resp. Ex. A at 3-4. Because S.S. "developed lipoatrophy at every site of intramuscular injections of clindamycin" within six to eight weeks, Dr. Okoye opined "this is the most likely inciting factor in the development of the lipoatrophy." Id. at 4. Dr. Okoye did not address or discuss how administration of clindamycin at the left hip can result in lipoatrophy on the left anterior thigh.

Dr. Okoye "ruled out" the November 2019 vaccinations as causative because S.S. did not develop lipoatrophy with every prior and subsequent vaccination. Resp. Ex. A at 4. Dr. Okoye acknowledged that the site of vaccinations were not documented. Id. However, she noted, "[t]he locations . . . presumably were on the anterior thighs (this is a common location for vaccine administration and was identified as the location of one of the vaccines by [Petitioner])." Id. It appears she opined all vaccines were presumably administered in the thighs. See id.

Dr. Okoye concluded "S.S. developed two areas of lipoatrophy [six to eight] weeks after two injections of clindamycin," which "were the most likely inciting factor in the development of the lipoatrophy given the timing and locations of the injections." Resp. Ex. A at 5.

IV. PARTIES' CONTENTIONS

A. Petitioner's Contentions

Petitioner contends "[t]he preponderance of evidence supports finding that the vaccinations . . . S.S. received on November 25, 2019[] were administered in her left thigh." Pet. Br. at 10. Petitioner argues there is "ample medical record evidence [that] documents and supports the site of vaccination administration to be the left thigh." Id. For support, Petitioner cites to visits with FNP Draper, Dr. Newborough, Dr. El Amm, and Dr. Davy, where Petitioner reported the vaccinations were given in the left thigh and each physician described the muscle atrophy and indentation to be in the left thigh post-vaccination. Id. at 10-18. Petitioner also notes photographic evidence of S.S.'s left thigh was provided. Id. at 10 (citing Pet. Ex. 17). Additionally, Petitioner cites to her expert's reports that support a finding that Petitioner's vaccinations on November 25, 2019 were administered in S.S.'s left thigh. Id. at 17-18. Thus, "[t]here is more than sufficient evidence in this record for a finding of fact that [S.S.'s] vaccinations were administered in the left thigh on November 25, 2019." Id. at 18 (emphasis omitted).

[8] Dr. Okoye agreed that although this was indicated to be the right thigh, all other subsequent medical records and photographs show the left thigh is the confirmed location. Resp. Ex. A at 2.

B. Respondent's Contentions

Respondent contends Petitioner has failed to establish by preponderant evidence that S.S.'s November 25, 2019 vaccines were administered at the site of her alleged injury. Resp. Br. at 3. Respondent agrees the record is clear that S.S.'s condition is associated with her left leg. Id. However, Respondent notes S.S.'s vaccination record does not indicate which, if any, vaccines were administered in her left leg on November 25, 2019. Id. (citing Pet. Ex. 8 at 1). Additionally, Petitioner has not provided a sworn statement that S.S. was vaccinated in her left thigh nor has Petitioner confirmed with OSDH that any of the vaccines were administered into S.S.'s left thigh. Id. Lastly, Respondent cites to the discrepancy of the location of injury (right versus left thigh) during a December 26, 2019 visit and argues this "makes it even less likely that S.S. was vaccinated at the site of her alleged injury."[9] Id. (citing Pet. Ex. 6 at 86-88).

V. DISCUSSION

A. Legal Standard

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Contemporaneous medical records, "in general, warrant consideration as trustworthy evidence." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that "medical records are accurate and complete as to all the patient's physical conditions"); Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (quoting Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir.

[9] Respondent fails to acknowledge his own expert, Dr. Okoye, opined that although the right thigh was noted, "the physical exam of the same note identifies the lesion on the left thigh. The left thigh is the confirmed location since the left thigh is consistently referenced in the subsequent medical records and the photographs (Ex 17) show the left anterior thigh." Resp. Ex. A at 2 (citing Pet. Ex. 6 at 86, 88).

1992))), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Cucuras, 993 F.2d at 1528.

Medical records that are clear, consistent, and complete should be afforded substantial weight. Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. Cucuras, 993 F.2d at 1528; see also Murphy, 23 Cl. Ct. at 733 ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.").

There are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell ex rel. Campbell v. Sec'y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Lowrie, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded to medical records, special masters are not bound rigidly by those records. Valenzuela v. Sec'y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec'y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

B. Analysis

For the following reasons, the undersigned finds the vaccinations at issue were administered in S.S.'s left thigh.

First, treating physicians and specialists consistently documented S.S.'s November 2019 vaccinations were administered in her left thigh.

S.S. first saw her PCP, FNP Draper for her injury. On December 26, 2019, S.S. saw FNP Draper for a "large, bruised area on her [left] thigh where she received her [six] month old immunizations [from] [OSDH]." Pet. Ex. 6 at 86. S.S. returned to her PCP on May 6, 2020 "due to left leg muscle [] separating due to Nov[ember] 25th [] [DTaP] [IPV] injections which caused

tissue damage" that "ha[d] extended into a larger area as she has grown." Id. at 120. Examination noted a "deformi[t]y in her left thigh due to tissue deterioration from injections in her thigh that caused muscle and tissue damage." Id. at 123. FNP Draper opined S.S. "ha[d] trauma on her left thigh due to Nov[ember] 25th inj[ections] of [DTaP] and [IPV]." Id. (emphasis omitted). By January 2021, her PCP noted S.S. had "chronic indentions due to vaccinations." Id. at 257.

S.S. also saw orthopedic specialist Dr. Davy. On February 3, 2020, Petitioner noted the injury and reason for the visit was "[i]ndentation on left leg from [six] month shots." Pet. Ex. at 49. Dr. Davy documented "at the time of her [six] month shots, which was a [DTaP] and [IPV], [S.S.] developed a dent in the anterior thigh." Id. at 46. Dr. Davy's assessment was "[s]oft tissue defect after prior immunization." Id.

On April 29, 2020, NP McKnight documented "atrophy to left upper thigh following immunizations." Pet. Ex. 24 at 16.

S.S. also saw two plastic surgeons. Plastic surgeon Dr. El Amm, on May 28, 2020, documented a "[l]arge left anterior thigh granuloma with cicatricial depression and fat atrophy extending into left inguinal post immunization." Pet. Ex. 1 at 36. Diagnosis was "[p]ost injection granulomatous reaction with significant cicatricial changes and fat atrophy." Id. at 38. Plastic surgeon Dr. Newborough, on June 16, 2020, wrote, "[Petitioner] state[d] that [S.S.] underwent her [six] month vaccinations including DTaP, [Hep] B[,] and [IPV] in her left medial upper leg . . . on November 25. By December 3[,] [S.S.] demonstrated what [Petitioner] describe[d] as a bruised area on the leg." Pet. Ex. 2 at 4. Assessment was "some type of reaction which has resulted in atrophy of the subcutaneous tissue and skin at the site of her previous vaccination." Id. at 5.

Overall, two NPs (including her PCP), an orthopedic specialist, and two plastic surgeons documented S.S.'s November 2019 vaccinations were administered in her left thigh at the location of her lipoatrophy.

The undersigned finds the contemporaneous medical records are clear, consistent, and complete, and should therefore be given significant weight. See Cucuras, 993 F.2d at 1528 (noting the weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions" and "[w]ith proper treatment hanging in the balance, accuracy has an extra premium").

Second, Petitioner's expert Dr. Amber opined the November 2019 vaccination were administered in the left thigh. He relied on S.S.'s medical records that consistently documented S.S.'s vaccines on November 25, 2019 were administered in her left thigh at the site of injury by various treating physicians.

Third, the undersigned is not persuaded by Respondent's expert, Dr. Okoye. Dr. Okoye opined an intramuscular injection of clindamycin in the left hip on October 28, 2019, not the November 2019 vaccinations, caused the localized lipoatrophy in the left thigh. She based her

opinion largely on the fact that a subsequent intramuscular injection of clindamycin in the buttock caused a localized lipoatrophy in the buttock in December 2020.

However, the undersigned finds a number of issues with Dr. Okoye's opinion. First, she failed to acknowledge that one indentation (lipoatrophy) was at the site of clindamycin injection (buttock) and the other occurred at a different anatomical location (left hip injection versus left thigh lipoatrophy).

She opined she "ruled out" the November 2019 vaccinations as causative because S.S. did not develop lipoatrophy with every subsequent vaccination. Resp. Ex. A at 4. However, she failed to explain how lipoatrophy would need to develop with every vaccination in order for one vaccination to cause lipoatrophy on one occasion. Lastly, she failed to adequately rule out the November 2019 vaccinations as causative because, as she opined, the anterior thighs are "a common location for vaccine administration." Id. And, although the vaccination record does not document the site any vaccination was administered, Dr. Okoye acknowledged the anterior thigh "was identified as the location of one of the vaccines by [Petitioner]." Id.

The undersigned does not find the "absence of a reference to a . . . circumstance"—here, site of vaccination—to be determinative since the official vaccination record from OSDH did not document the site of administration for any vaccination received by S.S. Shapiro, 101 Fed. Cl. at 538; see Pet. Ex. 8 at 1-2.

For the above reasons, the undersigned finds the vaccinations at issue administered in November 2019 were administered in the left thigh of S.S.

VI. CONCLUSION

In accordance with the undersigned's findings herein, Respondent shall indicate his position and/or file an amended Rule 4(c) report **by Wednesday, May 7, 2025**.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master